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Group News

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(Roche)

SIPPL

Roche announces settlement agreement with Promega

All PCR-related litigation resolved to satisfaction of both parties

SEP 2 1 2005

Roche today announced that it has settled with Promega all PCR-related litigation in the United States, Europe and Australia, including the original lawsuit initiated by Roche Diagnostics in 1992. The specific terms of the parties' agreement are confidential.

"Roche Diagnostics is pleased to reach this agreement with Promega and to close more than a decade of litigation between the two companies," said Heino von Prondzynski, CEO Division Roche Diagnostics and Member of Roche's Corporate Executive Committee. "Moving forward, we will focus on realizing the potential of our patent portfolio, which contains more than 800 patents and applications related to PCR products and methods, particularly those for real-time PCR technologies."

The amount of the settlement is covered by existing litigation provisions in the Roche financial statements. There are no additional impacts on Roche's net income from the announcement of this settlement.

About the Polymerase Chain Reaction Technology (PCR)

Polymerase Chain Reaction (PCR) is a Nobel-prize winning nucleic acid amplification technology that allows minute amounts of genetic material to be amplified into billions of copies in just a few hours. It has enabled many significant advances in the Human Genome project, DNA fingerprinting and in the diagnosis and monitoring of diseases such as AIDS and hepatitis.

PCR is most widely used to perform testing that identifies whether or not a specific gene sequence is present, such as that indicating if a patient has been infected with HIV. Beyond its wide medical applications, PCR has been used to help in our understanding of evolution, human migration and even for use in food safety.

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Roche has developed and encouraged the utility of PCR technology in a wide variety of areas through the company's global licensing programs. These programs, combined with a broad spectrum of scientific collaborations, postdoctoral fellowships, donations of reagents and visiting scientist programs, have successfully led to the development of new research products and revolutionary medical advances by readily placing PCR technology in the hands of innovative scientists worldwide.

While Roche's foundational PCR patents recently expired in the U.S., its patent portfolio contains more than 800 patents and applications related to PCR products and methods. Roche will realize the potential of its continuing patents through new licenses and other alliances that encourage the use of real-time PCR technologies.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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Additional information

- Roche Diagnostics: www.roche-diagnostics.com

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Media Release

Roche

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Basel, 13 September 2005

Pegasys plus Ribavirin awarded priority review status by Japanese Regulatory Agency

Priority review driven by compelling results from large phase III study in Japanese patients with Hepatitis C

Roche and Chugai announce today that the combination of Pegasys (peginterferon alfa-2a (40KD)) plus Copegus (ribavirin) has been awarded priority review status by the Japanese Regulatory Agency (MHLW). This brings forward the review time by approximately 6 months, with approval of the combination expected in Q3, 2006. This is good news for Japanese hepatitis C patients who may soon gain access to the world's leading hepatitis C combination treatments.

The filing was based on results from a landmark phase III Japanese clinical trial showing that 61% of treatment naïve genotype 1b patients who received Pegasys plus Copegus achieved a sustained virological response (which is indicative of a cure) compared with 26% of patients who received Pegasys alone. This is a breakthrough for combination treatment, providing the highest sustained virological response (SVR) rates reported in these patients. Patients with genotype 1b hepatitis C are considered to be a difficult group of patients treat.

The priority review granted for Pegasys plus Copegus demonstrates both the need for better treatment options for Japanese patients with hepatitis C, and the significance of the clinical trial results' said Ed Holdener, Head Global Pharmaceutical Drug Development at Roche. 'In close collaboration with Chugai, we are jointly committed to do the utmost for Japanese patients to have access to this highly effective treatment and therefore we welcome this news.'

The key results of the registration study are:

61% of patients who were treatment naïve, genotype 1b achieved an SVR when treated with
 Pegasys combination therapy. This is compared to an SVR of 26% for patients who received

Pegasys as monotherapy (P<0.001).

Difficult to treat patients with an initially high viral load also responded well to the
combination therapy with an SVR of 56% in the combination therapy group compared with
16% in the monotherapy group – a 3-fold increase in SVR

In a separate arm of the trial, Pegasys combination therapy also made a significant difference to the most difficult to treat patients

• In patients who had previously been treated with conventional interferon but either did not respond or relapsed after an initial response (so called 'nonresponders' or 'relapsers') the overall response rate was 54% with Pegusys plus ribavirin

This is the largest phase III clinical trial to examine the efficacy and safety profile of the combination of Pegasys plus ribavirin in Japanese patients. The trial was conducted in 43 centers in Japan and enrolled 300 patients.

About Pegasys

Pegasys is marketed in Japan by Chugai Pharmaceutical Co. Ltd. In Japan, Pegasys was approved in October 2003 with the indication for monotherapy treatment of chronic hepatitis C and is marketed under the tradename of Pegasys. Pegasys is the market leader worldwide in hepatitis C therapy.

About Ribavirin

Ribavirin is currently being developed in Japan by Chugai Pharmaceutical Co Ltd. Outside Japan, this drug is used as an anti-virus therapy for treatment of various types of infectious diseases. The ribavirin used in this trial is a ribavirin tablet (overseas trade name: "Copegus") developed by Roche for use in combination with Pegasys for the treatment of chronic hepatitis C.

About Hepatitis C in Japan

Hepatitis C is a potentially life threatening viral infection that can lead to liver inflammation, liver disease, cirrhosis or liver cancer. Transmitted primarily through infected blood, more than 170 million people world wide are infected making it more common than HIV virus.

About Genotype

Genotype is the classification of the hepatitis C virus and reflects differences in the genetic sequence of the virus. Genotype 1 hepatitis C is considered to be difficult to treat. The dominant genotypes in Japanese patients are 1b, 2a, and 2b. 1b in particular accounts for 70% of the total

chronic hepatitis C in Japan and is considered to be difficult to treat.

Chugai

Chugai Pharmaceutical Co., Ltd. is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products and in the therapeutic fields of oncology, renal diseases and bone/joint.

With pharmaceutical sales of 295 billion yen in 2004, Chugai has invested in research and development capabilities in the US and Europe, and has established sales and marketing operations in France, Germany and the UK. Chugai employs 5,327 employees world-wide.

Roche

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Further information

- -Roche Health Kiosk on Hepatitis C: www.health-kiosk.ch/start hepa.htm
- -WHO: Hepatitis: www.who.int/topics/hepatitis/en

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